

REMARKS

I. Status of the Claims and Support for the Amendment

Claims 12, 13, 16, 18–20, and 22–25 are currently cancelled.

Claims 1–6, 14, 17, and 21 are currently amended.

Claims 1–11, 14, 17, and 21 are currently pending.

Support for the amendment of the claims is found in the specification at page 5, lines 25–30, page 6, lines 24–26, page 8, lines 1–10, and page 9, lines 5–8.

Applicant explicitly reserves the right to pursue any cancelled material in one or more continuation or divisional applications.

II. Information Disclosure Statement

Referring to the Examiner's comments regarding the references listed in the Specification at pages 18–20, Applicant notes that this list is not intended to be considered an Information Disclosure Statement (IDS). Applicant's IDS and supplemental IDS were submitted in proper format on October 19, 2001 and October 24, 2002, respectively.

III. Rejection under 35 U.S.C. §112

Claims 1, 17, and 19 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are alleged to be indefinite on the grounds that it is confusing to state that the somatotropin is "biologically active in a cow". Further, the Examiner asserts that the claims are indefinite "since administering the compound does not necessarily reflect that milk production is induced. A step of induction is absent in the process." Applicant responds as follows

Firstly, rejection of claim 19 is moot as this claim is cancelled by the above Amendment. Further, as amended, claims 1 and 17 no longer recite that the somatotropin is "biologically

active in said mammal". Applicant believes that this obviates the Examiner's first §112 rejection. Finally, claims 1 and 17 now explicitly recite that the compounds are administered "to induce lactation". Applicant, believes that this amendment obviates Examiner's second §112 rejection. In view of the foregoing claim amendments, Applicant believes that the rejections of the claims under 35 U.S.C. §112, second paragraph, have been overcome and may now properly be withdrawn.

IV. Rejection under 35 U.S.C. §102

A. Claims 1, 2, 4-8, and 16 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by McFadden *et al.* (*J. Dairy Science* 78 (Suppl. 1):203, 1995). Specifically, it is alleged that:

McFadden *et al.* teach a method of inducing milk production in a non-pregnant cows [sic] (line 2) (present claim 16), the method comprising administering to cows a milk-secretion stimulation amount of estradiol and progesterone (line 5) administered via a vaginal sponge inserted more than 6 days (lines 5-7), and BST (bovine somatotropin) (line 3) (present claim 1) that is administered for 15 weeks (line 4) (present claims 2, 4 and 19) in a sustained release dose (lines 3-4) (present claims 6, 20) in at least four doses every bi-week (line 4) (present claim 5) and wherein the method also comprises administering a milk-secretion enhancing amount of a glucocorticoid approximately 6 days after the estradiol administration (line 6) (present claims 7 and 8).

Applicant respectfully traverses.

As set out in MPEP Chapter 2100:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a singly prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

MPEP §2131. Applicant asserts that this standard is not met for the current claims. The current claims require that the initial treatment, beginning on "day 0" include treatments with an estrogen-like agent (ELA), a progestational agent (PGA), and a biologically active somatotropin

(ST). In contrast *McFadden et al.* teaches that injection with somatotropin commence eight weeks “prior to initiation of milking” (*see* line 4). This is at least six weeks and two days prior to treatment with an ELA or a PGA, which started just 12 days prior to milking (lines seven and eight of *McFadden et al.* recite, *inter alia* that “[o]n d[ay] 10 of treatment, sponges were removed and milking was initiated 2 d[ays] later.”).

Thus, *McFadden et al.* is not anticipatory prior art under 35 U.S.C. §102 (according to the standards set out in *Verdegaal* and *Richardson*) because it does not teach same-day initiation of the administration of ST, ELA, and PGA. Accordingly, Applicant contends that *McFadden et al.* does not anticipate any of claims 1, 2, 4–8, and 16.

In view of the foregoing argument, Applicant believes that the rejection of claims 1, 2, 4–8, and 16 as being anticipated by *McFadden et al.* under 35 U.S.C. §102(b) has been overcome and may now properly be withdrawn.

B. Claims 1–3, and 19–21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Kensinger et al.* (*J. Dairy Science* 81 Supp. S1:210, 1998). Applicant respectfully traverses.

First, claims 19 and 20 are cancelled by the above amendment. Rejection of these claims is, therefore, moot and should be withdrawn. Second, *Kensinger et al.* does not teach the limitation that the mammal is a “dairy heifer” or “dairy reproductive cull”. Further, *Kensinger et al.* does not teach that treatment with somatotropin must begin on “day 0” and continue for “20 days or more”. Thus, *Kensinger et al.* does not describe “expressly or inherently” “each and every element as set forth in the claim”. Accordingly, Applicant contends that *Kensinger et al.* does not anticipate the amended claims under 35 U.S.C. §102(b). In view of this argument, Applicant asserts that this rejection may now properly be withdrawn.

C. Claims 1, 14, and 15 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Kumar *et al.* (*Indian Journal of Dairy Science*, 49:664–672, 1996). Applicant respectfully traverses.

Like Kensinger *et al.*, Kumar *et al.* does not teach the limitation that the mammal is a “dairy heifer” or “dairy reproductive cull”. Further, Kumar *et al.* does not teach that treatment with somatotropin must begin on “day 0” and continue for “20 days or more”. Thus, Kumar *et al.* does not anticipate the claims as currently amended. Accordingly, Applicant asserts that the rejection of claims 1, 14, and 15 under 35 U.S.C. §102(b) as being anticipated by Kumar *et al.* has been overcome and may now properly be withdrawn.

V. Rejection under 35 U.S.C. §103

A. Claims 1, 10–12 and 22–24 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McFadden *et al.* in view of Miller *et al.* (*J. Dairy Science* 81 (Suppl. 1):235, 1998). Specifically, the Examiner alleges that:

McFadden *et al.* teach a method of inducing milk production in cows (line 2) comprising administering to cows a milk-secretion stimulation [sic] amount of estradiol and progesterone (line 5) and BST (bovine somatotropin) (line 3) (present claim 1). McFadden *et al.* fail to teach a method wherein the cow is subject to photoperiods.

Miller *et al.* is then cited as teaching administering BST to cows and subjecting them to milk-stimulating photoperiods. However, the Examiner notes that Miller *et al.* “do not teach a method wherein estradiol and progesterone are administered in addition to the somatotropin and photoperiod exposure.” Nevertheless, the Examiner further argues that:

[g]iven the advantages of increasing milk yields in cows by administering BST and photoperiod exposure as taught by Miller *et al.* it would have been obvious to one of ordinary skill in the art at the time of the invention to use McFadden’s method of administering estradiol, progesterone and BST in addition to providing ambient, namely, approximately 12 hours of darkness and 12 hours of light, photoperiod exposure to yield increased milk production. Thus, the inventions in

claims 1, 10–12 and 22–24 were prima facie obvious to make and use at the time the claimed invention was made.

Applicant respectfully traverses.

Applicant directs the Examiner's attention to MPEP Chapter 700, which provides the following criteria that must be met in order to establish obviousness.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

MPEP §706.02(j)

Applicant notes that claims 12, 13, and 22–25 are cancelled by the above amendment, accordingly rejection of these claims is moot and should be withdrawn. With regard to claims 1, 10, and 11, Applicant asserts that the combination of the cited references fails to meet any, let alone all, of the requirements set out in MPEP §706.02(j).

Taking the §706.02(j) requirements in reverse order, there is nothing in the combination of *McFadden et al.* and *Miller et al.* which teaches or suggests treatment with somatotropin (ST), an estrogen-like agent (ELA), and a progestational agent (PGA), with administration of all compounds all beginning on day 0. On the contrary *McFadden et al.* teaches treatment with ST for at least 6 weeks prior to treatment of the animals with the ELA and PGA. Furthermore, there is nothing in the combination of the cited art that teaches or suggests induction of lactation in “dairy heifers” or “dairy reproductive culls.” Thus, the final requirement of MPEP §706.02(j) is not met with respect to the currently pending claims.

Next, there is nothing in the combination of the cited art that would provide one of ordinary skill in the art with a reasonable expectation that the claimed invention would successfully induce lactation in dairy heifers and dairy reproductive culls. At least two points support this position. First, as described above, the combination of the cited art does not teach the same treatment regimen as is currently claimed, therefore, the combination of the cited art provides no information with respect to the currently claimed invention. Second, the combination of the cited art provides no teaching or suggestion regarding the possibility of inducing lactation in dairy heifers or dairy reproductive culls. In fact, Miller *et al.* is not even drawn to induction of lactation, rather Miller *et al.* describes work done to increase milk production in cows that were already lactating (*see*, lines 4 and 5). McFadden *et al.* describes inducing lactation, but not in heifers or reproductive culls. Thus, there is nothing in the combination of the cited art which provides a reasonable expectation for the success of the instantly claimed method. Accordingly, MPEP §706.02(j)'s second requirement is not met.

Finally, MPEP §706.02(j)'s first requirement is not met because there is no teaching or suggestion, in the cited art, to combine those references so as to provide the instantly claimed invention. As discussed above, Miller *et al.* is drawn to increasing milk production in cows that are already lactating and McFadden *et al.* describes the use of a method wherein BST is administered at least 6 weeks before the ELA and PGA. There is nothing in the combination of these references which teaches or suggests the use of a method comprising commencing administration of ST, an ELA, and a PGA on the same day. *A fortiori*, there is nothing in the combination of the cited references that teaches or suggests using such a method to induce lactation in dairy heifers or dairy reproductive culls. Accordingly, the first requirement of MPEP §706.02(j) is not met.

In view of the foregoing arguments, Applicant believes that the rejection of claims 1, 10, and 11 under 35 U.S.C. §103(a) as being obvious over the combination of *McFadden et al.* and *Miller et al.* has been overcome and may now properly be withdrawn.

B. Claims 1, 10, 12, 13, and 22–25 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Kensinger et al.* in view of *Miller et al.* Specifically, the rejection states that

it would have been obvious to one of ordinary skill in the art at the time of the invention to use *Kensinger et al.*'s method of administering estradiol, progesterone and BST to fertile cows in addition to providing ambient, namely, approximately 12 hours of darkness and 12 hours of light, photoperiod exposure to yield increased milk production.

Applicant respectfully traverses.

First Applicant notes that rejection of claims 12, 13, and 22–25 is moot as they are cancelled by the above amendment. Thus, Applicant's traversal is with respect to the rejection of claims 1 and 10.

Applicant observes that *Kensinger et al.* provides no direction as to when treatment with bST is to commence or for how long it is to last. *Kensinger et al.* only indicates that there was a bST treated group of cows and a group of cows that was not treated with bST. The reference further indicates that "after 70 d[ays of milk production] all cows were treated with bST." (Lines 11–12). *Kensinger et al.* provides no indication as to when treatment with bST commenced nor as to whether treatment with bST was a single event, at intervals, periodic, or continuous. It is believed that the language of *Kensinger et al.* is consistent with any number of possible bST treatments and cannot be considered to disclose or suggest the treatment regime recited in the claims. Further, *Kensinger et al.* provides no suggestion that the methods described therein are useful for the induction of lactation in dairy heifers or dairy reproductive culls. In fact "[p]regnancy was confirmed in 14 of the first 20 cows, with 2.0 services per conception." Instead, the thesis of *Kensinger et al.* is that treatment with bST "augments milk yields in cows

induced into lactation". In contrast, the presently claimed invention provides a method for "inducing milk production...in dairy heifers and dairy reproductive culls."

There nothing in the combination of Kensinger *et al.* and Miller *et al.* that teaches or suggests a method comprising same-day administration of bST, a PGA, and an ELA commencing on day zero of the regimen. Likewise, there is nothing in the combination of these references which teaches administration of bST so as to provide bioavailability of "milk-secretion stimulating amounts beginning on day 0 and continuing for 20 days or more". Finally, as noted above, there is no suggestion of using the treatment of Kensinger *et al.* to induce lactation in dairy heifers or dairy reproductive culls.

Since the combination of the cited art does not teach or suggest a method of inducing lactation in dairy heifers or dairy reproductive culls, this combination cannot be deemed to provide a reasonable expectation that the instantly claimed method would be successful.

Finally, there is nothing in the combination of the cited art that provides any suggestion or motivation for modifying the combined teachings of the references so as to provide the invention of claims 1 or 10. That is, there is nothing in the combination of the cited art that suggests modifying the treatment of Kensinger *et al.* so as to provide the currently claimed treatment regimen.

In view of the foregoing analysis, it is Applicant's position that the combination of the cited art clearly fails to meet the elements required by §706.02(j) to establish a *prima facie* case of obviousness for the rejected claims. Accordingly, Applicant respectfully submits that the rejection of the claims as being obvious over Kensinger *et al.* and Miller *et al.* has been overcome and may now properly be withdrawn.

C. Claims 17 and 18 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McFadden *et al.* in view of Kumar *et al.* (*Indian Journal of Dairy Sci.* 49:664–672, (1996))

Specifically, the rejection states that:

[g]iven the advantages of administering glucocorticoid in addition to estradiol, progesterone and BST subcutaneously to increase milk production as taught by McFadden and the successful lower dosages of hormones to be administered taught by Kumar *et al.*, it would have been obvious to one of ordinary skill in the art at the time of the invention by applicant to administer subcutaneously lower dosages of BST, progesterone, glucocorticoid and estradiol to increase milk production.

Applicant respectfully traverses.

Given that claim 18 is cancelled by the above amendment, rejection of that claim is moot and should be withdrawn. Accordingly, Applicant's traversal is with respect to claim 17. The combination of Kumar *et al.* and McFadden *et al.* does not teach or suggest all of the limitations set out in claim 17. First, as noted *supra* McFadden *et al.* teaches the administration of bST starting fully six weeks prior to lactation. While, Kumar *et al.* recites that a "single dose of ...bovine somatotropin was administered on the very first day of treatment to study its effect on mammary gland development and subsequent milk production", this reference provides no teaching or suggestion for the use of a glucocorticoid. Thus, teachings of the combination of the cited art is in conflict with respect to both the timing of the bST treatment and the use and timing of the glucocorticoid.

Accordingly, there is nothing in the cited references that provides any motivation to combine them so as to produce the invention of claim 17. The combination of the cited references provides no suggestion to administer bST "beginning at day 0 and periodically thereafter as required to maintain the bioavailability of a milk-secretion stimulating amount through at least day 20 of the treatment". Further, there is nothing in the combination of the cited art that teaches or suggests a treatment to induce lactation in dairy heifers or in dairy

reproductive culls. Nor is there anything in the combination of cited art that provides a reasonable expectation that the method of claim 17 could be successfully used to induce lactation in dairy heifers or dairy reproductive culls.

It is, therefore, Applicant's position that the cited references cannot be combined so as to provide the instantly claimed invention. Nevertheless, even if their teachings are combined, they do not render the instantly claimed invention obvious under 35 U.S.C. §103(a) because, as recited in MPEP chapter 2100 the courts have held that: "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)." MPEP §2143.01.

In view of the foregoing arguments, Applicant believes that the rejection of claim 17 under 35 U.S.C. §103(a) has been overcome and may now properly be withdrawn.

D. Claims 1, 7, and 9 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McFadden *et al.* in view of Chakriyarat *et al.* (*J. Dairy Sci.* 61:1715-1724 (1978).

Examiner asserts that:

[g]iven the advantages of administering a combination of lactation-inducing hormones as taught by McFadden and the success of administering a small dosage of .028 mg/kg of dexamethasone as taught by Chakriyarat *et al.*, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer estradiol, progesterone, BST and a low dosage of about .028 mg/kg of dexamethasone to induce lactation in cows.

Applicant respectfully traverses.

As described above, the administration of bST, PGA, and ELA and the amount of glucocorticoid administered are not the only parameters constrained by the instantly claimed invention. The instantly claimed invention requires that the bST be given commencing on the same day as the PGA and ELA (a limitation not taught or suggested by the cited art). However,

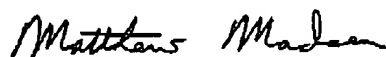
the combination of the cited art does not teach or suggest administration of bST, a PGA, and an ELA beginning on the same day nor does the art teach or suggest milk induction in dairy heifers or dairy reproductive culls. Therefore, Applicant contends that the combination of cited art fails to meet the criteria set out in *MPEP* §706.02(j) as being required to establish a *prima facie* case of obviousness. Accordingly, Applicant believes that the rejection claims 1, 7, and 9 as being unpatentable under 35 U.S.C. §103(a) has been overcome and may now properly be withdrawn.

VI. Conclusion

In view of the foregoing Amendments and Remarks, Applicant believes that all objections to the specification and claims and rejections of the claims have been overcome and that the case is in condition for immediate allowance. Accordingly, Applicant respectfully requests reconsideration of the instant Application and issuance of a Notice of Allowance therefor.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Matthew L. Madsen
Reg. No. 45,594
Patent Agent for Assignee
MONSANTO TECHNOLOGY LLC

HOWREY SIMON ARNOLD & WHITE, LLP
750 Bering Drive
Houston, Texas 77057-2198
(713) 787-1400

Date: October 1, 2003